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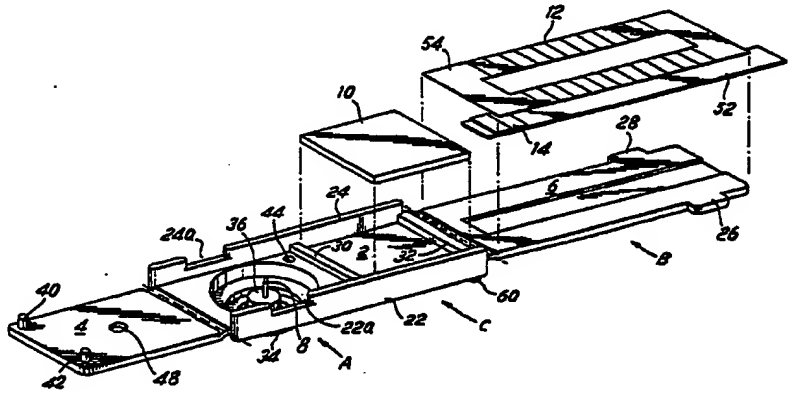


(57) Abstract

A diabetes testing pack comprises a disposable unitary structure of plastics material. The pack has three main areas (A, B and C) where the different phases of a diabetes test can take place. Area (A) is where the skin is punctured by a needle (8) to draw blood. Area (B) is where a drop of blood is deposited on a reagent (14) and the resulting colour change can be compared with a colour chart to determine blood glucose concentration. Area (C) is where the reagent strip can be wiped on a hygenic pad (10). The pack can be folded away in a sterilised wrapping before use and folded away in a hygenic manner for disposal after use.

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# APPARATUS FOR SAMPLING A FLUID

The present invention relates to apparatus for sampling a fluid, for example, for sampling and testing blood for a predetermined condition.

Kits for sampling and testing blood for diagnosing diabetes are known. Such kits employ a gadget for firing a needle to pierce the skin of the patient and a separate reagent strip onto which blood from the patients pierced skin can be dripped. The colour of the reagent strip when compared to a separate printed colour chart will indicate the likelihood of the patient having a diabetic condition. It is necessary to wipe the reagent strip with a separate absorbent material before making the comparison.

The disadvantage of this arrangement is that the kit is cumbersome to operate and the procedures to be adopted are not always clearly understood by the patient who normally has to operate the kit himself based on the written instructions accompanying the kit the parts for which are supplied in different quantities.

Furthermore, the gadget for piercing the skin is somewhat of a fearsome device in that it involves a trigger for releasing a spring loaded needle which upon release is directed at high speed into the skin in full view of the patient. This is often off-putting to the user.

According to the present invention there is provided apparatus for sampling a fluid by puncturing a skin through which said fluid can be obtained, the apparatus comprising a unitary pack defining at least two areas for conducting at least two phases of the sampling, a first area providing means for piercing the skin and a second area supporting a reagent which

upon contact with fluid released from the skin reacts to produce a colour change, the second area being also provided with a colour chart to allow a comparison to be made with the colour of the reagent.

Preferably the unitary pack defines a third area providing an absorbent pad.

Advantageously the piercing means comprises a housing providing a surface for contacting the skin, an aperture in said surface to provide access to a needle supported in said housing and means for imparting to said needle an acceleration to propel the needle through the aperture to puncture the skin and subsequently to withdraw the needle from the skin to enable said fluid to pass through the punctured skin.

The acceleration imparting means can comprise a flexible portion of predetermined configuration carrying said needle, said predetermined configuration being such that when pressure is applied to said portion in a direction to displace said needle towards the aperture, the resistance of said portion to displacement will increase progressively to a point at which inversion occurs and thereafter the resistance to pressure progressively decreases.

Advantageously the portion is of concentric stepped configuration.

According to the invention there is further provided a testing kit comprising a guide, a strip slidably supported on said guide, a reagent supported on said strip, and a colour chart located adjacent said strip, said strip being slidable relative to said colour chart to allow the colour of the reagent to be compared with predetermined colours on said chart.

Advantageously the reagent comprises a dry glucose sensitive enzyme reagent.

Preferably the chart holds the strip captive on said guide.

A diabetes testing pack embodying the invention will now be described, by way of example only, with reference to the accompanying diagrammatic drawings, in which:

Figure 1 is a perspective view of a diabetes testing pack in its closed configuration;

Figure 2 is a perspective view of the pack in its open configuration but with inserts omitted; and

Figure 3 is a perspective exploded view of the pack.

The diabetes testing pack shown in the drawings is arranged to sample the blood of a patient and to test it to ascertain whether or not the patient has a diabetic condition. The apparatus is in the form of a disposable unit so that once a sample of blood has been taken and tested the unit may be discarded.

The pack shown in the drawings (see Figure 3) has three main areas A, B and C where the different phases of a diabetes test take place. Area A is where the skin is punctured by a needle 8 to draw blood; Area B is where the blood is deposited on a reagent 14 and the resulting colour change can be compared with a colour chart 12 to determine the blood glucose concentration; and Area C is where the reagent strip can be wiped on a hygienic pad 10.

The pack comprises generally a one-piece moulding of plastics, for example, of polystyrene. The moulding includes a central region defining a base 2 and two lateral regions respectively defining

a cover 4 for the needle 8 and a lid 6 for the pack.

The base 2 has two longitudinally extending side walls 22 and 24. Each side wall is provided with a respective slot 22a and 24a for receiving respective ones of a pair of projections 26 and 28 of the lid 6. A pair of transversely extending dwarf retaining walls 30 and 32 together with the two side walls 22 and 24 define a generally square well for receiving the hygienic pad 10. Advantageously the pad 10 is made slightly oversize so as to be capable of being force fitted into the well and so be retained within the well. In a modification the pad 10 is secured to the floor of the well by an adhesive.

The base 2 to one side of the well defines a stepped dome portion 34 projecting from the underside. The dome portion 34 is defined by a plurality of concentric annular steps which terminate in a central thimble-shaped protrusion 36. The protrusion 36 projects inwardly so as to lie within the dome-shaped portion 34. The head of the protrusion 36 supports the needle 8 which is of stainless steel. The needle 8 can be embedded in the protrusion.

The cover 4 which lies to one side of the base 2 is connected to the base 2 by a thinned region of material which acts as a hinge. When the cover 4 is pivoted about the hinge axis, it fits between the two side walls 22 and 24 to cover the dome portion 34. The cover 4 is provided with a pair of frusto-conical locking projections 40 and 42 which are arranged to engage respective ones of a pair of openings 44 (only one shown) in the base 2. When the cover 4 is urged tightly against the base, the projections 40 and 42 will become wedged in the

openings 44 and so lock the cover in the position shown in Figure 2.

As shown in Figure 2 the upper face of the cover has a central dished area 46 with a central opening 48 which exposes the needle 8 below.

The lid 6 which lies on the opposite side of the base 2 to the cover 4 is also connected to the base 2 by a thinned region of material which also acts as a hinge. The lid 6 when pivoted about the axis of its hinge to close the open top of the base 2, will have its two projectory portions 26 and 28 engaging respective ones of the two slots 24a and 22a. The fit between the projections 26 and 28 and their respective slots 22a and 24a is arranged to be a tight fit so as to provide a latching action between the lid and the base.

The inner face of the lid 6 is provided with a shallow longitudinally extending channel 50 which is engaged by an elongate sliding strip 52.

The strip 52 is slightly longer than the channel and so projects from one end of the channel. The projecting portion of the strip acts as a tab which can be grasped by the hand of a user, to slide the strip up and down the channel 50.

The strip 52 has an area carrying the reagent 14 which is in the form of an enzyme coated reagent.

A rectangular card 54 bearing the colour chart 12 has a rectangular opening through which the strip 5 can be viewed. The card 54 is adhesively secured to the inner face of the lid 6 to hold the strip 52 captive in the channel 50.

The chart 12 is defined by a series of different coloured rectangular areas and the colour change along the length of the chart is progressive.

The base 2 is provided with a pair of feet 60 (only one shown) having the same depth as the domed portion 34 to allow the base 2 to stand stably on a flat surface.

The whole pack as shown in its closed state in Figure 1 is hermetically sealed within a sleeve of plastics material (not shown) to maintain the pack in a hygienic state.

In operation a patient releases the pack from its sleeve (not shown) and opens the lid 6.

The patient then places his thumb or some other part of his anatomy from which blood is to be drawn, on to the dished area 46. Then using a free finger the patient applies pressure to the underside of the body 2 in the region of the domed portion 34. The domed portion initially offers increasing resistance to the applied pressure until it is deformed to an extent where it starts to undergo an inversion. At this point, resistance to pressure decreases rapidly with the consequent effect that the protrusion 36 is accelerated towards the cover 4. The needle 8 which is rigid with the protrusion undergoes the same acceleration to which the protrusion 36 is subjected and is projected through the opening 48 into the skin of the patient. The movement of the needle 8 is halted when the protrusion 36 strikes the underside of the cover 4.

When the pressure on the domed portion 34 is released the the domed portion 34 will recover under its natural resilience and accordingly the protrusion 18 will withdraw the needle 8 from the skin.

As the domed portion 34 returns to its original configuration a blood droplet will form on the thumb.

The patient then applies the blood droplet to the reagent 14 and waits for a short period for a reaction to take place.

Once the reaction has taken place the patient grasps the tab of the strip 52 and pulls the reagent 14 along the colour chart until it reaches a position where the colour of the chart matches that of the reagent.

The chart will then indicate (by means not shown) if and how much insulin the patient will need.

Once the test has been completed the patient closes the lid to reseal the unit which may then be discarded. This provides a hygienic method of discarding the waste material of the test.

It will also be appreciated that different patients have different thicknesses and toughnesses of skin, accordingly needles of different length may be used and the force applied to the needle varied.

Units with different properties in this respect may be colour coded with different colours for easy identification.

It will also be appreciated that the units described are not limited for use in testing for a diabetic condition but can be used to test for other conditions.

It will further be appreciated that the portion 34 may be of smooth dome-shaped configuration instead of the stepped configuration shown in the drawings.

It will be appreciated that the needle and the spring can both be of plastics material or a composite of plastics and other material.

CLAIMS

1. Apparatus for sampling a fluid by puncturing a membrane through which said fluid can be obtained, the apparatus comprising a unitary pack defining at least two areas for conducting at least two phases of the sampling, a first area providing means for piercing the membrane, and a second area supporting a reagent which upon contact with fluid released from the membrane reacts to produce a detectable change in a parameter of the reagent, the second area being also provided with a chart showing variations in said parameter to allow a comparison to be made with the detectable parameter of the reagent.

2. Apparatus according to Claim 1 wherein said membrane comprises skin and said parameter comprises colour.

3. Apparatus according to Claim 1 or to Claim 2 wherein the unitary pack defines a third area providing a pad of absorbent material.

4. Apparatus according to any preceding claim wherein the piercing means comprises a housing providing a surface for contacting the skin, an aperture in said surface to provide access to a needle supported in said housing and means for imparting to said needle an acceleration to propel the needle through the aperture to puncture the skin and subsequently to withdraw the needle from the skin to enable said fluid to pass through the punctured skin.

5. Apparatus according to Claim 4 wherein the acceleration imparting means can comprise a flexible portion of predetermined configuration carrying said needle, said predetermined configuration being such that when pressure is applied to said portion in a

direction to displace said needle towards the aperture, the resistance of said portion to displacement will increase progressively to a point at which inversion occurs and thereafter the resistance to pressure progressively decreases.

6. Apparatus according to Claim 5 wherein the portion is of concentric stepped configuration.

7. A testing kit comprising a guide, a strip slidably supported on said guide, a reagent supported on said strip and arranged to receive a fluid to effect a change in colour of the reagent, and a colour chart located adjacent said strip, said strip being slidable relative to said colour chart to allow the colour of the reagent to be compared with predetermined colours on said chart.

8. A kit according to Claim 7 wherein the chart holds the strip captive on said guide.

9. A kit according to any preceding Claim wherein the reagent comprises a dry glucose sensitive enzyme reagent.

10. A diabetes testing pack incorporating apparatus or a kit according to any preceding Claim.

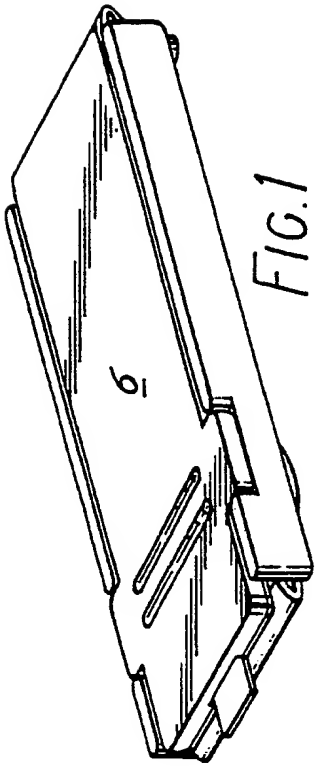


FIG.1

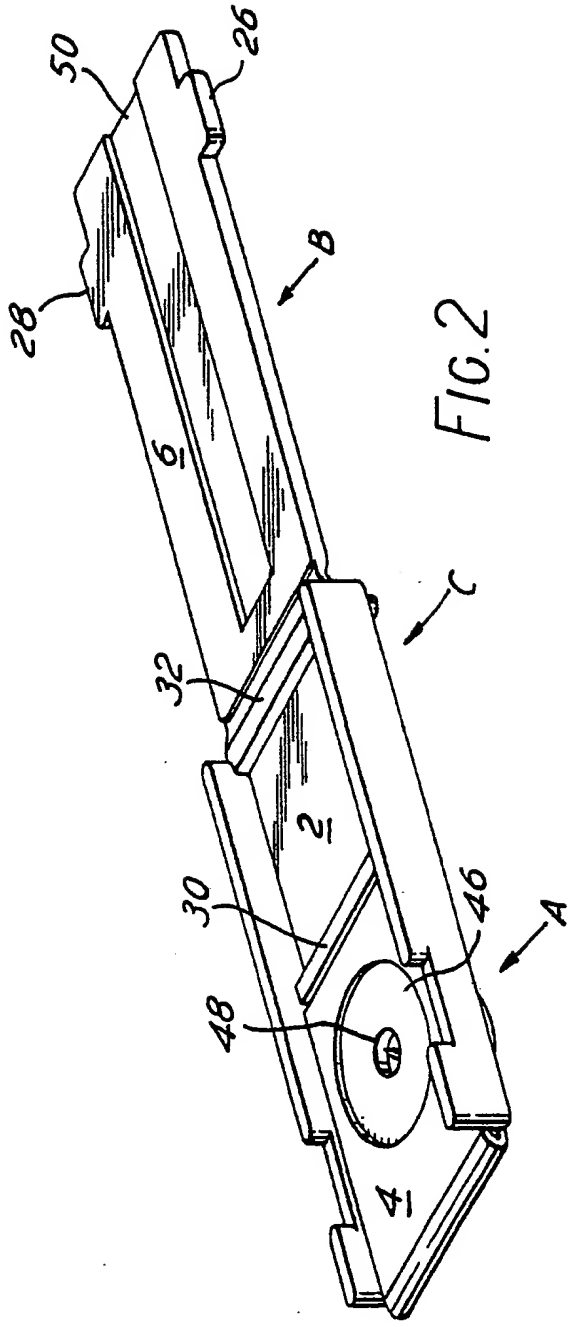


FIG.2

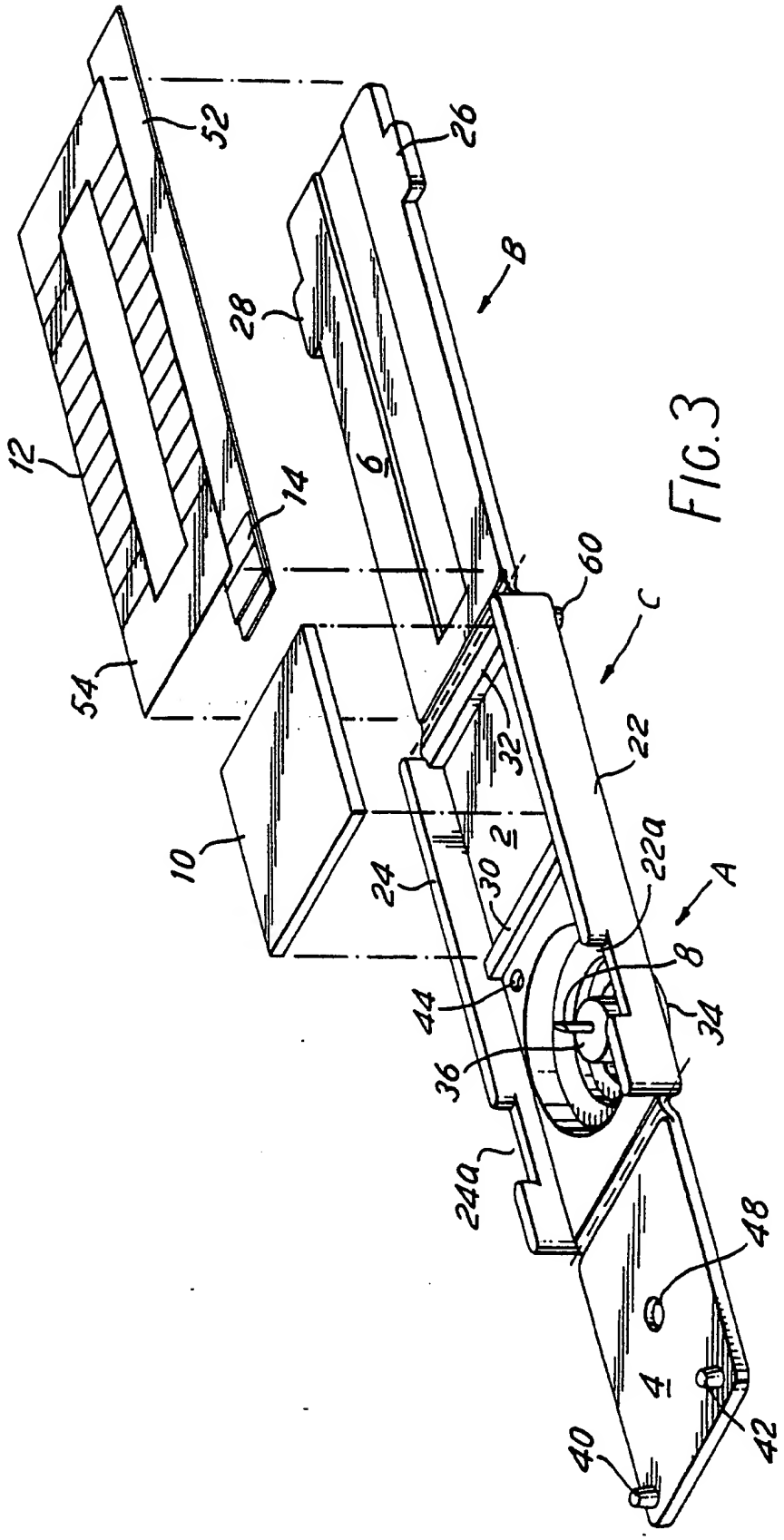


FIG.3

# INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 85/00318

## I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 B 5/14; C 12 Q 1/54; G 01 N 33/52

## II. FIELDS SEARCHED

Minimum Documentation Searched [7]

| Classification System | Classification Symbols |
|---|---|
| IPC[4] | A 61 B<br>C 12 Q<br>G 01 N |

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

## III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

| Category [10] | Citation of Document, [11] with indication, where appropriate, of the relevant passages [12] | Relevant to Claim No. [13] |
|---|---|---|
| X | EP, A1, 0097748 (G.J. SLAMA) 11 January 1984, see abstract; page 1, lines 4-6; page 4, lines 7-29; page 6, line 23 - page 7, line 18; figures 1-5 | 1,2,4,7-10 |
| A | US, A, 3094121 (W.K. BLUMENSTEIN et al.) 18 June 1963, see column 1, lines 34-45; column 3, lines 48-64; figure 8 | 4-6 |
| A | US, A, 3236237 (R.P. DUNMIRE) 22 February 1966, see column 3, lines 24-36,47-53; column 4, lines 21-44; column 5, line 64 - column 6, line 15; figures 1-5 | 4-6 |
| A | US, A, 3933594 (T.W. MILLIGAN et al.) 20 January 1976, see abstract; column 1, lines 60-68; column 2, lines 1-23; column 3, lines 26-63; column 4, lines 20-23; figures 1-4 | 1-3,7-9 |
| A | US, A, 3791933 (R.H. MOYER et al.) 12 February 1974, see abstract; column 1, lines 29-65; column 2, lines 33-45; column 3, lines 55-67; column 4, lines 14-34,48-64; | 3,7-9 |

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## IV. CERTIFICATION

| Date of the Actual Completion of the International Search | Date of Mailing of this International Search Report |
|---|---|
| 17th October 1985 | 20 NOV. 1985 |
| **International Searching Authority** | **Signature of Authorized Officer** |
| EUROPEAN PATENT OFFICE | G.L.M. Kruydenberg |

International Application No. PCT/GB 85/00318

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

| Category * | Citation of Document, with indication, where appropriate, of the relevant passages | Relevant to Claim No |
|---|---|---|
| | column 5, lines 16-26; column 9, lines 14-20; figures 4,8 -- | 3,7-9 |
| A | US, A, 3917453 (T.W. MILLIGAN et al.) 4 November 1975, see abstract; column 1, lines 5-13; column 3, lines 36-57; column 4, lines 15-17; figures 1-3 | 3,7-10 |

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/GB 85/00318 (SA 10160)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 11/11/85

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| Patent document cited in search report | Publication date | Patent family member(s) | | Publication date |
|---|---|---|---|---|
| EP-A- 0097748 | 11/01/84 | None | | |
| US-A- 3094121 | | None | | |
| US-A- 3236237 | | None | | |
| US-A- 3933594 | 20/01/76 | US-A- | 3996006 | 07/12/76 |
| | | LU-A- | 77199 | 17/08/77 |
| | | NL-A- | 7704608 | 01/11/77 |
| | | BE-A- | 853945 | 26/10/77 |
| | | FR-A,B | 2349830 | 25/11/77 |
| | | DE-A- | 2714555 | 10/11/77 |
| | | AU-A- | 2451177 | 26/10/78 |
| | | JP-A- | 52132579 | 07/11/77 |
| | | AU-B- | 502691 | 02/08/79 |
| | | CH-A- | 616236 | 14/03/80 |
| | | CA-A- | 1071911 | 19/02/80 |
| | | GB-A- | 1585127 | 25/02/81 |
| | | AT-B- | 360174 | 29/12/80 |
| | | SE-A- | 7704665 | 29/10/77 |
| US-A- 3791933 | 12/02/74 | None | | |
| US-A- 3917453 | 04/11/75 | None | | |